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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,921	07/11/2003	Shin Hirayama	240292US0CONT	2418
22850	7590	03/01/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,921	<b>Applicant(s)</b> HIRAYAMA ET AL.	
	<b>Examiner</b> Susan Coe	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/186,702.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-11-03</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The preliminary amendment filed January 8, 2004 has been received and entered.
2. Claims 1-16 have been cancelled.
3. Claims 17-30 have been added and are currently pending.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 17-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of obesity using D-cysteinolic acid, does not reasonably provide enablement for the prevention of obesity using D-cysteinolic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are broadly drawn to the prevention of obesity. The use of "prevention" requires that the specification show that the claimed invention is able to prevent obesity in each and every possible occurrence. It is well known in the art that the causes of obesity are varied

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and are linked to factors other than diet such as family history and underlying disease states.

Applicant's specification has not addressed all of the possible causes of obesity or shown that D-cysteinolic acid is able to prevent obesity caused by all of these causative factors. Thus, a person of ordinary skill in the art would be forced to experiment unduly to determine if applicant's invention functions as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 is indefinite because applicant has not defined what temperatures are considered to be encompassed by "hot." Thus, the metes and bounds of the claim are unclear.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17, 18, 20 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03118319 A2 in view of US Pat. No. 4,220,653.

JP '319 teaches that derivatives of D-cysteinolic acid function as inhibitors of gastric juice secretion. The active ingredient is administered in combination with ingredients such as lactose which is a food product. The reference does not specifically teach that D-cysteinolic acid itself is able to function as a gastric juice secretion inhibitor. However, the derivatives taught are closely related structurally to D-cysteinolic acid itself (see English abstract). Due to the significant overlap in structural characteristics and functional groups, a person of ordinary skill in the art would reasonable expect that D-cysteinolic acid itself would function as a gastric juice secretion inhibitor. Thus, the artisan of ordinary skill would be motivated to use D-cysteinolic acid as a gastric juice secretion inhibitor.

JP '319 also does not specifically teach that gastric juice secretion inhibitors are used to treat obesity. However, US '653 teaches using gastric juice secretion inhibitors to treat obesity (see column 2, lines 7-24). Thus, it was known in the art at the time of the invention that gastric juice secretion inhibitors are used to treat obesity. Therefore, based on what is taught by the combination of the references, a person of ordinary skill in the art would reasonable expect that D-cysteinolic acid would be useful in treating obesity. Due to this reasonable expectation of success, the artisan of ordinary skill would be motivated to use D-cysteinolic acid to treat obesity.

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7. Claims 21, 22, 24-26, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03118319 in view of US Pat. No. 4,220,653 as applied to claims 17, 18, 20, and 30 above, and further in view of JP 200104601 A.

As discussed above, the combination of JP '319 and US '653 is considered to teach using D-cysteinolic acid to treat obesity. However, the references do not teach using sea lettuce or a sea lettuce extract to treat obesity. JP '601 teaches that D-cysteinolic acid is contained in sea lettuce and can be extracted using hot water. Based on this teaching by JP '601, a person of ordinary skill in the art would be reasonably expect that using sea lettuce and a hot water extract of sea lettuce to treat obesity would be successful because they would contain the active ingredient, D-cysteinolic acid. Thus, a person of ordinary skill in the art would be motivated to use sea lettuce and sea lettuce extracts to treat obesity.

JP '601 does not specifically teach using the hot water temperatures claimed by applicant. The water temperature of a hot water extraction is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal water temperature to use in order to best achieve the extraction of D-cysteinolic acid. Therefore, this optimization of extraction temperature is considered to be an obvious modification of what it taught by JP '601.

8. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "Susan D. Coe".

Susan Coe, Examiner

February 24, 2004